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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/854,280	05/10/2001	Jian Chen	P1381R1C2	8242

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EXAMINER

JIANG, DONG

ART UNIT PAPER NUMBER

1646

DATE MAILED: 09/20/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/854,280

Applicant(s)

CHEN ET AL.

Examiner

Dong Jiang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 61-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 61 and 68-71 is/are rejected.
- 7) ☒ Claim(s) 62-67 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6 & 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED OFFICE ACTION

Applicant's election without traverse of Group II invention, directed to SEQ ID NO:3 and 4, in Paper No. 9, filed on 12 August 2002 is acknowledged. Applicant's amendment in paper No. 9 is acknowledged and entered. Following the amendment, the original claims 43-60 are canceled, and the new claims 61-71 are added.

Currently, claims 61-71 are pending and under consideration.

Formal Matters:

Priority

This application claims priority to US provisional applications 60/085,579 and 60/113,621, and US application 09/311,832. For the following reasons, the Examiner finds that the present claims 60-70 are not supported by all priority applications.

US provisional application 60/085,579 filed on 15 May 1998 does not disclose SEQ ID NO:3 and 4 as claimed in the instant application. US provisional application 60/113,621, filed on 23 December 1998 merely discloses the sequences of the present SEQ ID NO:3 and 4, and provides no specific, substantial and credible utility thereof. Therefore, it does not support the present invention in the manner required by 35 U.S.C. 101 and 112, first paragraph. As such, the claims of the instant application are not entitled to the benefit of the filing date of the two claimed US provisional applications.

Double Patenting Rejections:

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

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Claims 62-67 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 54, 76, 80, 81, 85 and 86 of copending Application No. 09/311,832. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Objections and Rejections under 35 U.S.C. 112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 70 and 71 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 70 is indefinite because it is unclear whether the Baculovirus-infected insect cell is infected by the virus prior the introduction of the vector of claim 68.

Claim 71 is indefinite for failing to adequately point out what applicants see as the invention, as the host cell may produce polypeptides other than the polypeptide encoded by the transformed or transfected expression vector. The claim should be amended to indicate the identity of the polypeptide being produced.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 61 and the dependent claims 68-71 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited in scope to nucleic acids of SEQ ID NO:4 and ATCC 203552, and nucleic acids encoding a polypeptide of SEQ ID NO:3, does not reasonably provide enablement for all nucleic acids "having at least 80% amino acid sequence identity to" above sequences. The specification does not enable any person skilled

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in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The factors considered when determining if the disclosure satisfies the enablement requirement and whether any necessary experimentation is "undue" include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

Claims 61 and 68-71 are directed to nucleic acids variants of SEQ ID NO:4 and ATCC 203552, and nucleic acids encoding a polypeptide of SEQ ID NO:3, which have at least 80% sequence identity to said nucleic acids (as claim 61, for example). The claims read on any or all variants meeting the sequence limitation, and encoding polypeptides either with or without functional activity.

However, as the specification teaches that IL-17C (PRO1122) of SEQ ID NO:3 induces production of TNF- α (Example 10), and the utility of the nucleic acids is to produce the functional polypeptide encoded thereby, it provides no guidance as to how the skilled artisan could use an inactive polypeptide variant of SEQ ID NO:3, encoded by the claimed nucleic acid variants, as no functional limitation associated with the variants in the claims. Therefore, it would require undue experimentation to practice this invention as claimed, because the skilled artisan would have no reasonable expectation of being able to use the nucleic acid variants encoding polypeptides that are inactive for any purpose stated in the specification.

Due to the lack of direction/guidance presented in the specification regarding to how to use the inactive variants of SEQ ID NO:3, the absence of working examples directed to same, and working examples directed to the active variants or fragments of SEQ ID NO:3, the nature of the invention which is drawn to a polypeptide supposed to be useful in research and clinical applications, the lack of predictability, and the breadth of the claims which embrace a broad class of structural variants, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

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The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Ruben et al. (WO9961617-A1, provided by applicants) discloses a polynucleotide (Figure 6A-B) comprising nucleotides 17-1047 of SEQ ID NO:4 of the instant application with 98.9% sequence similarity, and encoding a human IL-21 protein, which amino acid sequence is 100% identical to SEQ ID NO:3 of the present invention (see appended computer printout of sequence search results).

Conclusion:

Claims 62-67 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

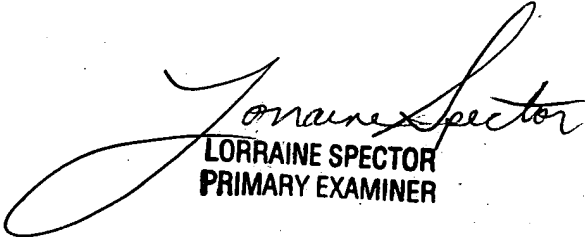
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Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 703-305-1345. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


LORRAINE SPECTOR
PRIMARY EXAMINER

DJ
9/17/02